



ACCREDITATION SCHEME FOR LABORATORIES

Technical Notes MED 002

Specific Criteria for Cytopathology Section

Technical Notes MED 002 – Cytopathology, 29 March 2019
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1. Introduction & Scope

- 1.1 a) This document describes the specific requirements to be complied by cytopathology laboratory to be accredited.
- b) The International Standard 'ISO 15189 Medical laboratories – Particular requirements for quality and competence', other MEDICAL Series Technical Notes published by SAC-SINGLAS shall be studied in conjunction with this document.

2. General Technical Note : Medical 001

2.1 Please refer **General Technical Note: Medical - 001** for the following:

- Personnel
- Accommodation & Environmental Conditions
 - Physical Facilities and Laboratory Safety
- Laboratory Equipment – Calibration & Maintenance
- Pre-examination Procedures
 - Requisitions, Collection and Handling of Specimens
- Examination Procedures
 - Test Methods and Method Validation
- Assuring Quality of Examination Procedures
 - Quality Control, Proficiency Testing, Reagents and Reference Materials
- Post-examination Procedures
 - Retained Samples and Waste Disposal
- Reporting of Results

3. Personnel

- 3.1 Refer to Personnel in **General Technical Note: Medical - 001**. . In addition to that the following is applicable to cytopathology laboratory.
- 3.2 The LD or Pathologist will be responsible for cytology and histology reports. They shall be SAB certified in pathology
- 3.3 The Pathologist and Cytotechnologist must participate in continuing education in cytology dedicated training and updates.
- 3.4 The pathologist or a designated alternative must be available every working day.
- 3.5 Each screener whether Cytotechnologist or Pathologist involved in primary screening shall not screen more than 70 slides / per person / 24 hours.
- 3.6 An in-house programme should be undertaken if the Cytotechnologist has not screened smears for 3 months. For an absence from screening for more than 6 months, a formal (external) update programme is recommended.

3.7 The pathologist should see a minimum number of 20 abnormal smears per month.

3.8 The Cytotechnologist should read a minimum of 3000 slides per year.

4. Accommodation and Environmental Conditions

4.1 Refer to Accommodation and Environmental Conditions in **General Technical Note: Medical - 001**. . In addition to that the following is applicable to cytopathology laboratory.

Safety

4.2.1 Refer to Accommodation & Environmental Conditions - Physical Facilities and Laboratory Safety in **General Technical Note Medical 001**. In addition to that, the cytopathology laboratory shall comply with the following:-

4.2.2 Appropriate extraction systems shall be in place to minimize the levels of noxious vapours.

5. Laboratory Equipment

5.1 Refer to Laboratory Equipment in **General Technical Note: Medical - 001**. . In addition to that the following is applicable to cytopathology laboratory.

Automated Screening

5.2.1 The laboratory shall only use automated systems that have been validated and verified for the scope of testing carried out by the laboratory. It shall be familiar with the limitation of the system and use it appropriately.

6. Pre-examination Procedures

6.1 Refer to Pre-examination Procedures – Requisitions, Collection and Handling of Specimens in **General Technical Note: Medical - 001**.

7. Examination Procedures

7.1 Refer to Examination Procedures in **General Technical Note: Medical - 001**. . In addition to that the following is applicable to cytopathology laboratory.

7.2 There shall be a documented policy for ensuring that non-gynaecologic specimens with a high potential for cross-contamination are processed and stained separately from other specimens.

8. Assuring Quality of Examination Procedures – Quality Control and Proficiency Testing

8.1 Refer to Assuring Quality of Examination Procedures - Quality Control, Proficiency Testing, Reagents and Reference Materials in **General Technical Note: Medical - 001**. In addition, quality control measures must be in place and documented to ensure good technical quality of slides produced.

- 8.2 If the laboratory is performing immunohistochemical stains, it shall be enrolled in a quality assurance programme for immunohistochemistry.
- 8.3 The Laboratory shall be enrolled in SAC-SINGLAS recognised quality assurance programmes or its equivalent.
- 8.4 A rescreen of 10% of the normal cervical smears shall be done regularly by a suitably trained Cytotechnologist or Pathologist.
- 8.5 Correlation of cervical smears with biopsies shall be done whenever the biopsies are available.
- 8.6 A review of all previous cytology should be carried out, especially in the case of high grade squamous intraepithelial lesion, and the review should be documented.
- 8.7 All non-gynaecologic slides shall be reviewed and the report signed by a pathologist.
- 8.8 Effort shall be made to correlate non-gynaecologic cytopathology findings with histological and clinical findings.

9. Post-examination Procedures

- 9.1 Refer to Post-examination Procedures in **General Technical Note: Medical - 001**.

10. Reporting of Results

- 10.1 Refer to Reporting of Results in **General Technical Note: Medical - 001**. In addition to that the following is applicable to cytopathology laboratory.
- 10.2 In the case of a cervical smear, conventional and liquid based tests should be addressed if they are used.
- 10.3 Only non-malignant (normal and inflammatory) smears may be reported by suitably trained Cytotechnologist.
- 10.4 All abnormal cervical smears and non-gynaecological smears shall be reported by a Pathologist or a designated qualified physician.
- 10.5 The cervical PAP smear shall be reported using current standard terminology and classification.
- 10.6 All reports shall be easily retrievable by name or identification number or accession number.

10.7 Retention of Laboratory Reports and Materials

- 10.7.1 Slides should be archived in or by the reporting laboratory. If these are archived outside the laboratory, there must be a documented procedure for the retrieval of slides.
- 10.7.2 Should a laboratory cease business, the laboratory should take all measures as are reasonable and necessary to ensure that the medical records of every patient are properly transferred to the healthcare establishment indicated by the patient's clinician to patient; or the stewardship of another accredited laboratory.
- 10.7.3 The table below refers to the minimum retention period for materials and records. Laboratories are to retain records and materials for a longer period of time than specified, especially when patient care needs so warrant it.

Microfilm and electronic records in place of hard copies are acceptable provided they are maintained securely, are readily accessible and are the exact duplicates of the reports sent out.

MATERIALS	CYTOLOGY
Cytologic material e.g. sputum, fluid	7 days
IMF Slides	7 days
Gynaecologic and non-gynaecologic glass slides	5 years
Fine needle aspiration glass slides	10 years
Reports	20 years